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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/651,563	08/29/00	WANG	T 210121.478C1

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EXAMINER	
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ART UNIT	PAPER NUMBER
1631	5

DATE MAILED: 04/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/651,563	Wang et al
Examiner	**Group Art Unit**
Michael Borin	1631

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-60* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-60* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

Claims 1-60 are currently pending.

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1,2 and claims 17-20(in part), drawn to isolated polypeptide encoded by a polynucleotide from an EST library, and compositions thereof, classified in class 530, subclass 330.

II. Claims 3, drawn to isolated polypeptide, classified in class 530, subclass 330.

III. Claims 4-10, drawn to polynucleotides, expression vectors and cells comprising the vector, classified in class 536, subclass 23.1 and class 935, subclass 66, and claim 17-20 (in part), drawn to compositions comprising the polynucleotide.

IV. Claims 11, drawn to an antibody or fragment thereof, classified in class 530, subclass 388.1, claims 17-20 (in part), drawn to compositions comprising the antibodies and claims 54-57 drawn to diagnostic kit containing said antibodies, classified in class 435, subclass 810.

V. Claims 12-15, drawn to a fusion protein, classified in class 530, subclass 330, and claim 17(in part), drawn to pharmaceutical composition comprising the fusion protein.

VI. Claim 16, drawn to isolated polynucleotide encoding product of Group IV, classified

in class 536, subclass 23.1, and claims 17-20 (in part), drawn to compositions comprising the polynucleotide.

VII. Claims 21,22,31 (in part) drawn to method of use of composition comprising polypeptide of Group I, classified in class 514, subclass 02.

VIII. Claims 21,22,31 (all in part) drawn to method of use of composition comprising polynucleotide of Group III, classified in class 514, subclass 44.

XIX. Claims 21,22,31 (all in part) drawn to method of use of composition comprising antibodies of Group IV, classified in class 514, subclass 02.

X. Claims 21,22,31 (all in part) drawn to method of use of composition comprising fusion protein of Group V, classified in class 514, subclass 02.

XI. Claims 21,22,31 (all in part) drawn to method of use of composition comprising polynucleotide of Group VI, classified in class 514, subclass 44.

XII. Claims 23-28 drawn to composition comprising antigen-presenting cell, classified in class 435, subclass 325.

XIII. Claims 29,30 and claim 31(in part), drawn to method of inhibiting cancer in a patient using the cells of Group XII, classified in class 435, subclass 325.

XIV. Claims 32-34 drawn to method of removing tumor cells from biological sample, using product of Group I, classified in class 514, subclass 02.

XV. Claim 35(in part), drawn to method of stimulating T cells using polypeptide of Group I, classified in class 514, subclass 02.

XVI. Claim 35 (in part), drawn to method of stimulating T cells using polynucleotide of Group III, classified in class 514, subclass 44.

XVII. Claim 35 (in part),drawn to method of stimulating T cells using antigen-presenting cells of Group XII, classified in class 435, subclass 325.

XVIII. Claim 36 drawn to T cell population, classified in class 435, subclass 325.

XIX. Claim 37, drawn to method of inhibiting cancer in a patient using cells of claim 36, classified in class 435, subclass 325.

XX. Claims 38,39(in part), drawn to method of inhibiting development of cancer using polypeptide of Group I, classified in class 514, subclass 02.

XXI. Claims 38,39(in part), drawn to method of inhibiting development of cancer using polynucleotide of Group III, classified in class 514, subclass 44.

XXII. Claims 38,39 (in part),drawn to method of inhibiting development of cancer using antigen-presenting cells of Group XII, classified in class 435, subclass 325.

XXIII. Claims 40-47, drawn to method of screening utilizing polypeptide of Group I, classified in class 435, subclass 7.1

XXIV. Claims 48-53, drawn to method of screening utilizing polynucleotides of Group II, classified in class 435, subclass 6.

XXV. Claims 58,59, drawn to short oligonucleotides capable of hybridizing to polynucleotide of Group III, classified in class 536, subclass 23.1, and claim 60 drawn to diagnostic kit containing said short oligonucleotides, classified in class 435, subclass 810.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-VI, XII, XVIII, XXIV are drawn to independent and/or patentably distinct products since each of these products possesses different structure, and/or physico-chemical properties, and/or capable of separate manufacture and/or use. Additionally, these different groups do not share a common structure which elicits a common activity. The examination of the Groups will require different searches of the US Patents and scientific literature and would require consideration of different patentability issues.

Groups I and II are drawn to polypeptides which do not have common core structure as

claimed. Majority of the polynucleotides recited in claims 1,2 are not associated to much narrower genus of peptides of Group II. Until products of specific SEQ ID Nos. are elected, it is burdensome to establish such association between polypeptides claimed in claims 1, 2 and claim 3.

Groups III and XXV are drawn to polynucleotides having different length; there is no common core structure for the polynucleotides as claimed. The inventions are drawn to independent and/or patentably distinct polynucleotides since each would be expected to possess distinctly different structure, and/or physico-chemical properties, and/or capable of separate manufacture and/or use. Accordingly, a reference teaching, e.g., a 40-mer oligonucleotide will not teach or suggest polynucleotides comprising such oligonucleotide. Therefore, each group requires non co-extensive sequence and literature searches.

Groups I/II and III/V are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Groups III/V, the critical feature is a polynucleotide whereas for Group I the critical feature is a polypeptide. It is acknowledged that various processing steps may cause a polypeptide of group I to be directed as to its synthesis by a polynucleotide of Group III, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two

groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Inventions I and IV are separate and distinct as the polypeptides of Invention I are structurally and biochemically different than the antibodies of Invention IV. While the antibodies may bind to the polypeptides of Invention II, the biochemical activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner.

Inventions II/VI and IV are separate and distinct, as the claims of Inventions II/VI are drawn to polynucleotides, while the claim of group IV is drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention IV would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

The inventions of Groups I/II and V are patentably distinct from each other because of the materially different structures of the compounds they are claiming. The Groups are drawn to independent and/or patentably distinct polypeptides since each would be expected to possess distinctly different structure (e.g., amino acid content, secondary and tertiary structure), and/or physico-chemical properties, and/or capable of separate manufacture and/or use. Where inventions

are related as disclosed but are distinct as claimed, restriction may be proper. (MPEP 806). The groups require non-coextensive search as a reference teaching the polypeptide of Group I will not teach a fusion protein comprising thereof; conversely, a reference teaching fusion polypeptides will not teach the particular fragment of Group I/II. Note, that the inventions may be related as disclosed but patentably distinct as claimed.

The methods of Groups VII-XI,XIII-XVII, XIX-XXIV differ in the method objectives, and/or method steps and parameters, and/or in the reagents used.

Inventions I-VI, XII, XVIII, XXIV and inventions VII-XI,XIII-XVII, XIX-XXIV are related as products and respective processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant cases the products as claimed can be used in a materially different processes of using that product, and claimed methods, in most cases, are alternative methods of using the same product (e.g., methods of Groups VII, XX, XXIII are alternative methods of use of product of Group I). Further, for a given product (e.g., polypeptide) methods of use of another product (e.g., antibody) are separate and distinct as the method utilizes another product. As such the Inventions would require search in separate and non-

overlapping areas, imposing an undue search burned upon the examiner if not restricted.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on a plurality of independent and/or patentably distinct sequences. Each peptide or nucleic acid sequence is independent and/or patentably distinct because they are unrelated compounds, there is no disclosed core structure required for a common utility, and because each of these compounds possess different structure and/or physico-chemical properties, and/or capable of separate manufacture and/or use. **For an elected Group the Applicants must further elect a single amino acid or nucleic acid sequence.**

MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Examination will be restricted only to a Group drawn to elected sequences.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, and the necessity for non-coextensive literature searches restriction for examination

purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Mr. Michael Woodward, can be reached at (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER